

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

8799 '99 JUN -2 A11:23

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. **THIS IS NOT A SAFETY ISSUE!!** As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Signed: Mark Handke

State of Residence: Michigan

Citizens and doctors need access to compounded medications available in whatever state they are compounded. These compounds are often necessary and effective when patented treatments are toxic, poorly tolerated or ineffective. I have a family member who suffered over 20 years with no effective treatment through patented medications. Our doctor prescribed a compounded medication, and it provided relief and control of her condition. It changed her life, but it's only available out of state. It's derived from soybeans. Please don't stop our access! Please don't harm our health with your regulation (MOU)!

In a time when medication costs can devastate people economically, compounded medications are often much less expensive than patented compounds.

The consequences of the above MOU is we suffer.

C3046

5/25/99

98N-1265



Mr. Mark Handler
4925 Christie Ct.
Midland, MI 48640

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Food and Drug Administration
5630 Fishers Lane, Room 1061
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